

REMARKS

The claims have been amended to more clearly characterize the composition. Support for the insertion of the word “dried” is found throughout the specification, for example, page 4, line 16 and line 23; page 5, line 17 and line 37; page 6, line 21, and in many other locations. Support for the requirement that the composition be stable for weeks at room temperature is found on page 6 at lines 1-9. The language “consisting essentially of granules comprising” is present to denote that the microorganisms are in the form of granules; as opposed to a composition where only a part of it is these granules and it contains a multitude of free microorganisms in other conditions.

Applicants note that the Examiner indicated at the interview that she views “consisting essentially of” as the same as “comprising” however, upon reflection, applicants believe this is not the case. “Consisting of” is so strict that even if one or two loose microorganisms were found in the composition, the claims could be avoided. It is believed understood, generally, that “consisting essentially of” means, in this case, that the fungi or bacteria have all been extruded into granule form, though one or two may have escaped at some point. Their escape would be insufficient to alter the basic nature of the composition. This is standard patent terminology as stated by the standard treatise Chisum on Patents, § 8.06[1][b][ii] on pages 8-189 of the 2002 revision:

A variant of the strict closed claim is created by the use of the phrase “consisting essentially of” which covers combinations with some additional elements but excludes “additional unspecified ingredients which would affect the basic and novel characteristics of the product defined in the balance of the claim.”

Citing, for example, *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 588 F.Supp. 1455, 221 USPQ 426 (N.D. Tex. 1983), aff'd, 750 F2d 1569, 1574, 224 USPQ 409, 412 (Fed. Cir. 1984)

the phrase “consisting essentially of” “excludes ingredients that would materially affect the basic and novel characteristics of the claimed composition.”

As it is understood that what is intended to be excluded is such ingredients, and such ingredients only, it is believed that the term “consisting essentially of” is appropriate in this case.

Support for the porosity origin is found on page 20, beginning at line 27 and continuing to page 21, line 3. No new matter has been added and entry of the amendment is respectfully requested.

The Rejection Under 35 U.S.C. § 103

All pending claims were rejected over the combination of Barclay with Carduck, *et al.*, Akimoto, *et al.*, Casey, *et al.*, and Remington, *et al.*. It is believed that at least the amendments to the sole independent claim, claim 68, clearly place the invention outside of the cited art. Applicants will begin with the teachings of each document, keeping in mind that it is the combination of teachings of the cited documents that is made the basis for rejection. However, it may be helpful simply to review the thrust of each document as applicants see it.

Starting with Barclay, the composition referred to in column 12 is designed to be a food product, as opposed to a dried composition that is suitable for storage and later extraction. The Examiner is, of course, correct that the components, which may be desired to be extracted, are overlapping with the nutritive components of the feed; nevertheless, the compositions of Barclay are designed so that the nutritive components will be immediately available upon ingestion by an animal. The thrust of the Barclay disclosure is that a chloroplast-containing organism is a suitable source for certain nutrients. This type of organism is excluded from the present claims. In discussing how such nutritive components might be garnered, Barclay offers two alternatives. In

one, which is similar to the type of activity contemplated by applicants, the biomass harvested from culture can be simply dried and in order to extend its shelf-life be “acidified...and/or pasteurized or flash heated to inactivate enzymes and then canned, bottled or packaged under a vacuum or non-oxidizing atmosphere” (column 11, lines 50, *et seq.*). The lipids containing omega 3 unsaturated fatty acids could then be extracted directly from the biomass (column 13, lines 13, *et seq.*). There is no discussion of extrusion in this context. Alternatively, the biomass is converted into a composition intended as feed.

In the only discussion of extruding the biomass, which appears in column 12, lines 32-59, the description is clearly focused on preparing a feed composition, not a composition that will preserve the essential nutrients on long storage. As described, the cells are extruded without any discussion of any measures being taken to inactivate enzymes or kill the cells as required by the claims. (The cells must be dead.) There is apparently no concern with regard to inactivating enzymes or otherwise making certain that the nutrients are preserved over the long haul. There is no teaching that the cells be non-disrupted; indeed, there is a specific teaching that the degree of disruption is variable (lines 43-44). The description actually teaches against killing the cells by pasteurization or other means as set forth in lines 50-54, where it is specified that the mixture of the biomass and dry ground grain be directly extruded to reduce costs. There appears to be no step of drying the extruded mixture as required by the claims. Thus, the composition obtained by Barclay differs from that of the claims in several ways: it is not dried, it is not reported to be stable for weeks on storage at room temperature (indeed it is used directly as a feed), the microorganisms are not dead and may not be non-disrupted. If the granules are porous, Barclay is silent on it and they may well not be, since according to the present specification, the porosity in the claimed

composition arises upon drying. Thus, one might suppose that the composition obtained by Barclay is not porous. There is also no specification of the diameter of the granules. These differences are over and above the acknowledged difference that the Barclay microorganisms are chloroplast-containing, as opposed to the bacteria and fungi in the present compositions. The thrust of the teaching of Barclay is that these chloroplast-containing organisms are useful in animal feed, and not that it is particularly advantageous to prepare a granulated composition.

These deficiencies are not remedied by Carduck, even if Carduck is combined with Barclay. Carduck teaches granulated compositions of live yeast which are dried. Thus, one claim parameter that is clearly not supplied by Carduck is that the fungi or bacteria are dead. The object of Carduck is to provide sufficient porosity that the extended surface areas are at least 1.5-20, optionally 2-10, times the dimensional areas of the granules (column 4, lines 12-15). This is accomplished by mixing gases such as air, CO₂, or N₂ with the moist yeast so that upon extrusion, the confined gas is freed and escapes to the surface. Although the degree of porosity is not given in terms of percentage, it should be clear that the nature of the porosity obtained by pumping gas into the mixture prior to extrusion and drying will be different in nature and from the porosity obtained in the drying of extruded mixtures without having gas pumped in. Comparison of figures 1 and 2 in the Carduck patent illustrates the difference between the porosity obtained after gas is pumped in as taught by Carduck and that obtained by simple extrusion and drying as in the composition claim. As described in Carduck, figure 1 shows extruded strands of moist yeast, extruded without the incorporation of gas, and figure 2 shows moist yeast extruded from masses containing incorporated gas. (Although the description of the figures refers to "moist" yeast, it is believed these differences will be maintained when the composition is dried – otherwise there would be no point in pumping

gas into the composition). Thus, the process limitation, while understandably not preferred by the Office, is meaningful in this case, especially in view of the teachings of Carduck itself. Thus, at least two parameters not specified in Barclay are also not specified in Carduck - the microorganisms are not dead and the porosity is of a different nature. No specification of desired diameters is provided by Carduck either.

Thus, when combined, Barclay and Carduck do not teach all of the elements set forth in the claims. And aside from the teaching of the invention itself, there is no reason to combine them. Clearly there is no suggestion in the documents themselves that the combination be made, the problems to be solved is completely different * (Barclay to provide animal feed and Carduck to keep yeast alive so that it may be reconstituted) and neither is a particularly well known publication in the art. Thus, none of the three criteria enunciated by the Court in *In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998) is present here. The only reason these are combined is that the invention teaches a particular granulated composition and each of these documents incidentally employs extrusion of microorganisms. The thrust of Barclay is elsewhere – that certain chloroplast-containing organisms may be used in animal feed and the thrust of Carduck is elsewhere – that pumping gas into a composition of live yeast is desirable prior to performing an extrusion process. Only the teaching of the invention would motivate their combination, and applicants are confident that the Office is aware that this is not a proper motivation.

The additional documents, Akimoto and Casey, are simply cited to show that useful nutritional elements, specifically highly unsaturated fatty acids, are found in yeast and *Aspergillus*. This is acknowledged prior art and does nothing to remedy the failure of Barclay and Carduck, even

* In both cases, the problem to be solved is different from that solved by the present invention.

taken together, to teach the essential parameters set forth in the claims. Of course, neither Akimoto nor Casey teach these essential parameters either, nor are they asserted to do so.

Finally, Remington is cited to show that it is possible to control the diameter of extruded granules. But there is no teaching in Remington that the required dimensions are desirable. Applicants' invention does not reside in a new method to control granule size, but rather as to this feature, the required dimensions of the granules themselves. This feature of the claims is not taught anywhere in any document cited by the Office.

In summary, no document cited teaches the following claim parameters:

1. A composition stable for weeks on storage at room temperature;
2. A porosity of 15-50% generated by drying of the granular composition;
3. A granular composition where the fungi or bacteria are dead; and
4. The granules must have a diameter between 0.1 mm-12 mm.

None of these parameters is incidental – the last three are essential for achieving the desired properties, including the first. The porosity and dimensions are required for ease of extraction and manipulation (see page 4, lines 28-32, page 6, line 30-page 7, line 1). Pasteurization to kill the organisms is clearly taught as advantageous on page 10, lines 1-5 and lines 15-16. The advantages of non-disruption are also taught on page 6, lines 10-17. The only document that teaches that the microorganisms be non-disrupted is Carduck which is directed to an entirely different purpose – to keep the yeast alive. Thus, the combination of “dead and non-disrupted” is not taught by any combination of the cited art.

In summary, none of the documents cited by the Office alone or taken together result in all (or even most) of the limitations of the independent claim. These limitations are not meaningless – they provide desired properties to the composition. Further, there is no motivation to combine the primary and secondary documents; they are directed to entirely different purposes from each other and from the present invention. For this reason, applicants believe no *prima facie* case has been advanced by the Office and it is believed that claims 69-95 are in a position for allowance.

CONCLUSION

Applicants again wish to express their appreciation to Examiner Marx for the helpful discussion at the interview. As discussed, additional parameters have been added to claim 68 further to characterize the claimed composition. In view of the failure of the art to teach the complement of parameters set forth in the claims, it is believed that the pending claims are in a position for allowance and passage of these claims to issue is respectfully requested. If changes in claim wording in respect to clarity, etc., are desired, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. **251502006900**.

Respectfully submitted,

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